



Patient Information Sheet

Tipranavir (marketed as Aptivus)

This is a summary of the most important information about Aptivus. For details, talk to your healthcare professional.

What Is The Most Important Information I Should Know About Aptivus?

Patients taking Aptivus, together with 200 mg Norvir (ritonavir), may develop severe liver disease that can cause death. If you develop any of the following symptoms of liver problems, you should stop taking Aptivus/ritonavir treatment and call your doctor right away: tiredness, general ill feeling or “flu-like” symptoms, loss of appetite, nausea (feeling sick to your stomach), yellowing of your skin or whites of your eyes, dark (tea-colored) urine, pale stools (bowel movements), or pain, ache, or sensitivity on your right side below your ribs. If you have chronic Hepatitis B or C infection, your doctor should check your blood tests more often because you have an increased chance of developing liver problems.

What Is Aptivus?

Aptivus is a medicine called a “protease inhibitor” that is used to treat adults with Human Immunodeficiency Virus (HIV). Aptivus blocks HIV protease, an enzyme which is needed for HIV to make more virus. When used with other anti-HIV medicines, Aptivus may reduce the amount of HIV in your blood and increase the number of CD4+ cells. Reducing the amount of HIV in the blood may keep your immune system healthy, so it can help fight infection. Aptivus is always taken with Norvir (ritonavir) and at the same time as Norvir. When you take Aptivus with Norvir, you must always use at least 2 other anti-HIV medicines.

Aptivus does not cure HIV infection or AIDS. You may still get infections or other conditions common in people with HIV. Aptivus does not reduce the chance of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood.

Who Should Not Take Aptivus?

Do not take Aptivus if you:

- are allergic to tipranavir or any of the other ingredients in Aptivus.
- are allergic to ritonavir (Norvir)
- have moderate to severe liver problems

- take any of the following types of medicines because you could have serious side effects:
 - Migraine (headache) medicines called “ergot alkaloids”. If you take migraine medicines, ask your healthcare professional if any of them are “ergot alkaloids”.
 - Halcion (triazolam)
 - Hismanal (astemizole)
 - Orap (pimozide)
 - Propulsid (cisapride)
 - Seldane (terfenadine)
 - Versed (midazolam)
 - Pacenone (amiodarone)
 - Vascor (bepridil)
 - Tambocor (flecainide)
 - Rythmol (propafenone)
 - Quinaglute (quinidine)

What Are The Risks?

Aptivus can cause serious problems such as:

- **Liver problems, including liver failure and death.** Your doctor should do blood tests to monitor your liver function during treatment with Aptivus. Patients with liver diseases such as Hepatitis B and Hepatitis C may have worsening of their liver disease with Aptivus and should have blood tests more often.
- **Rash.** Mild to moderate rash, including flat or raised rashes or sensitivity to the sun, have been reported in approximately 10% of subjects receiving Aptivus. Some patients who developed rash also had joint pain or stiffness, throat tightness, or generalized itching.
- **Increased bleeding in patients with hemophilia.** This can happen in patients taking Aptivus or other protease inhibitor medicines.
- **Diabetes and high blood sugar (hyperglycemia).** This can happen in patients taking Aptivus or other protease inhibitor medicines. Some patients have diabetes before starting treatment with Aptivus which gets worse. Some patients develop diabetes during treatment with Aptivus. Some patients will need new diabetes medicine or changes in their current diabetes medicine.
- **Increased blood fat (lipid) levels.** Your doctor should do blood tests to monitor your blood fat (triglycerides and cholesterol) during treatment with Aptivus. Some patients taking Aptivus have large increases in triglycerides and cholesterol. The long-





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term chance of having a heart attack or stroke due to increases in blood fats caused by Aptivus is not known at this time.

- **Changes in body fat.** These changes have happened in patients taking Aptivus and other anti-HIV medicines. The changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known.
- **Common side effects such as** diarrhea, nausea, vomiting, stomach pain, tiredness, and headache. Women taking birth control pills may get a skin rash. You should report any new or continuing symptoms to your doctor right away. The list of side effects is not complete. Ask your healthcare professional for more information.

What Should I Tell My Healthcare Professional?

Tell your healthcare professional about all of your medical conditions, including if you:

- have liver problems or are infected with Hepatitis B or Hepatitis C. These patients may have worsening of their liver disease.
- are allergic to sulfa medicines.
- have hemophilia. Aptivus may cause increased bleeding.
- have diabetes. Aptivus may worsen your diabetes or high blood sugar levels.
- are pregnant or planning to become pregnant. It is not known if Aptivus can harm your unborn baby. You and your doctor will need to decide if Aptivus is right for you. If you take Aptivus while you are pregnant, talk to your doctor about how you can be in the Antiretroviral Pregnancy Registry.
- are breast-feeding. Do not breast-feed if you are taking Aptivus. You should not breast-feed if you have HIV because of the chance of passing the HIV virus to your baby. Talk with your doctor about the best way to feed your baby.

- are using estrogens for birth control or hormone replacement. Women who use estrogens for birth control or hormone replacement have an increased chance of developing a skin rash while taking Aptivus. If a rash occurs, it is usually mild to moderate, but you should talk to your doctor as you may need to temporarily stop taking either Aptivus or the other medicine that contains estrogen or female hormones.

Are There Any Interactions With Drugs Or Foods?

Tell your healthcare professional about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Aptivus and many other medicines can interact. Sometimes serious side effects will happen if Aptivus is taken with certain other medicines (see “Who Should Not Take Aptivus?”).

Women taking birth control pills need to use another birth control method. Aptivus makes birth control pills work less well.

How Do I Take Aptivus?

- Take Aptivus exactly as your doctor has prescribed.
- You must take Aptivus at the same time as Norvir (ritonavir). The usual dose is 500 mg (two 250 mg capsules) of Aptivus, together with 200 mg (two 100 mg capsules or 2.5 mL of solution) of Norvir, twice per day.
- Aptivus with Norvir must be used together with other anti-HIV medicines.
- Aptivus comes in a capsule form and you should swallow Aptivus capsules whole. Do not chew the capsules.
- Always take Aptivus with food.
- Do not change your dose or stop taking Aptivus without first talking with your doctor.
- If you take too much Aptivus, call your doctor or poison control center right away.
- If you forget to take Aptivus, take the next dose of Aptivus, together with Norvir (ritonavir), as soon as possible. Do not take a double dose to make up for a missed dose.
- You should NEVER stop taking Aptivus or your other HIV medicines without talking with your doctor.

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*Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
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